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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,422	06/26/2003	David F. McComsey	ORT-1222 USA DIV	6306

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,422	MCCOMSEY ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-37 and 39-46* is/are rejected.

7)☒ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 2/16/06, claims 18-26 have been cancelled, and claims 27-46 added. Claims 27-46 are now pending.

Applicants' arguments filed 2/16/06 have been considered and found persuasive in part. The previously imposed §112, second paragraph rejections are withdrawn.

✦

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-37, 39-42, 44-46 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have provided data (table 1, pages 9-11) which shows that some of the compounds induce platelet aggregation in vitro, and data (table 2, page 12) which shows that other compounds inhibit platelet aggregation.

Applicants have also provided articles and a discussion which tends to support the proposition that if one can succeed in inhibiting platelet aggregation *in vitro*, success in the treatment of certain platelet mediated disorders may be possible, including those

recited in claims 37 and 42. The issue, however, is that applicants own data supports a conclusion of "unpredictability" with regard to inhibition of platelet aggregation, induction of platelet aggregation, and treatment of the various diseases listed in claims 37 and 42. That is, the data in table 2 supports the conclusion that the hematologist of ordinary skill will fail to induce platelet aggregation. The data in this table supports the proposition that failure in this regard is inevitable. For the skilled artisan endeavoring to induce platelet aggregation, the data in table 2 supports the conclusion that "unpredictable" results will be obtained. Similarly, for the skilled artisan endeavoring to inhibit platelet aggregation, the data in table 1 supports the conclusion that "unpredictable" results will be obtained. And similarly, for the skilled artisan endeavoring to treat the diseases recited in claims 37 and 42, the data in table 1 suggests that, not only will he (or she) fail to improve the patient's condition, the patient's condition is likely to be exacerbated.

Notwithstanding the foregoing, there is perhaps an argument to be made that if the skilled hematologist or cardiovascular specialist were to undertake the expenditure of "undue experimentation", he (or she) could test every compound that is encompassed by claims 27 and 37 to determine which of these inhibit platelet aggregation, and which induce it. Having done this, he could then select only those that inhibit platelet aggregation for administration to the subject. However, to do this would, as

indicated, require the expenditure of "undue experimentation". Further, there is no suggestion in any of the claims that such a step (to determine aggregation propensity) be undertaken. In the case of claim 37, for example, the claim calls for administration of any of the compounds, even those that will exacerbate the patients' condition. In order to practice the full scope of claim 37, the skilled artisan would have to test a large number of compounds, and equally important, a large number of animal or human subjects.

In addition to the foregoing, claims 27, 30-32, 35 and 36 recite the term "therapeutically effective", without reciting the objectives of the therapeutic efficacy. Given that no objectives are recited, it follows therefrom that all objectives are encompassed. Included would be neurodegenerative diseases such as the following:

> AIDS Dementia Complex (a.k.a. HIV-Associated Dementia) Amyotrophic Lateral Sclerosis (a.k.a. Lou Gehrig's Disease), Alzheimer 's Disease, Huntington's Disease, Multiple Sclerosis, Parkinson's Disease, Creutzfeldt-Jakob disease, progressive supranuclear palsy, Creutzfeldt-Jakob disease, multifocal leukoencephalopathy, diffuse and transitional Lewy body disease, frontotemporal degeneration, corticobasal degeneration, multiple system atrophy, Pick Disease, argyrophilic grain disease and corticobasal degeneration. In addition, experimental automimmune encephalomyelitis is an animal model of multiple sclerosis.

It remains the case that applicants have not shown how the skilled artisan can use the compounds to treat any of these. Thus, even if there is an argument to be made that claims 28 and 33 would be enabled in the absence of the term "therapeutically effective", the fact

remains that this term is present in these claims (or the claims that they are dependent on), and so rejection remains justified.

As for claims 29, 34, 39 and 44, these claims recite the term recite the term "consisting essentially of". As such, these claims encompass any compound, enabled or not.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. In accordance with the foregoing, "undue experimentation" would be required to practice the claimed invention.

✧

Claims 27-36, 39, 43, 44 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 27, 30-32, 35 and 36 recite the term "therapeutically effective". This renders the claims indefinite as to the objectives of the therapeutic efficacy.
- Claims 29, 34, 39, 44 recite the term "consisting essentially of". However, this fails to set the metes and bounds of the claims.
- In claim 43, "X" is undefined in the last compound.

✧

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

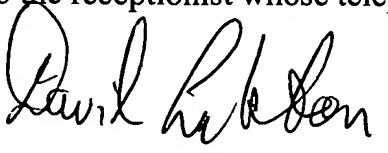
Two of the references were stricken from the IDS because they were not received.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER